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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/925,143 | 08/09/2001 | Robert B. Schock | DATA_53_CIP | 3516 |

7590 10/02/2002

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EXAMINER

PATEL, NIHIL B

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3743 | |

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/925,143 | SCHOCK ET AL. |
| | Examiner Nihir Patel | Art Unit 3743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-18 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

| | |
|----------------|-----------------|
| Species | Figure(s) 1 |
| | Figure(s) 2, 2A |
| | Figure(s) 4 |
| | Figure(s) 5A |
| | Figure(s) 5B |
| | Figure(s) 6 |
| | Figure(s) 7A |
| | Figure(s) 7B |
| | Figure(s) 7C |

Sub-species

| |
|--------------------------|
| Figure(s) 1A, 1B, 1C |
| Figure(s) 3A, 3B, 3C, 3D |

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Abraham Ronai on September 26, 2002 a provisional election was made with traverse to prosecute the invention of figure 4, claims 1 through 18. Affirmation of this election must be made by applicant in replying to this Office action. Claim 5 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 5, 7, 9, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Referring to claims 1 and 5, there is insufficient antecedent basis for limitations “a distal end” and “a proximal end”.

Referring to claim 4, there is insufficient antecedent basis for limitations “a proximal end”.

Referring to claim 7, there is insufficient antecedent basis for limitations “a wire”.

Referring to claim 9, there is insufficient antecedent basis for limitations “a fiberoptic sensor”.

Referring to claims 10 and 11, there is insufficient antecedent basis for limitations "a fiberoptic sensor", "a fiberoptic fiber", and "a gas shuttle lumen".

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Andrews et al. U.S. Patent No. 5,865,721. Andrews discloses an intra-aortic balloon catheter that comprises a balloon membrane (18), a tube (12 and 14), a tip (20), and a stylet (28), a distal end of the tube is connected to a proximal end of the balloon membrane (18), the tip (20) is connected to a distal end of the balloon membrane (18), a distal end of the stylet (28) is connected to the tip (20), a proximal end of the stylet is connected to a distal end of the tube (12 and 14), the stylet (28) being more flexible towards the distal end than the proximal end. Refer to figures 1 through 9 and columns 5,6 and 7.

Referring to claim 4, Andrews shows that a reinforcement ring (21) is disposed within a distal end of the tube, a proximal end of the stylet being fixed to an inner surface of the ring. Refer to column 5 lines 1 through 10.

Referring to claim 6, Andrews shows that the tube (12 and 14) is reinforced by a wire and comprises an exposed portion and an unexposed portion and wherein the stylet comprises at least a portion of the exposed portion. Refer to figure 1.

Referring to claim 7, Andrews shows that the tube (12 and 14) is reinforced by a wire and comprises an exposed portion and an unexposed portion and wherein at least a portion of the exposed portion projects from the unexposed portion and connects to the stylet. Refer to figure 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. U.S. Patent No. 5,865,721 in view of Fischer Jr. U.S. Patent No. 5,544,648.

Andrews discloses the applicant's invention as claimed with the exception of providing a removable gas insert disposed within at least a portion of the tube.

Fischer discloses a device for intratracheal ventilation and intratracheal pulmonary ventilation including reverse venturi that does provide a removable gas insert disposed within at least a portion of the tube. Therefore it would be obvious to modify Andrews invention by providing a removable gas insert disposed within at least a portion of the tube so that one knows the limitations of the invention.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. U.S. Patent No. 5,865,721 in view of Griffin III U.S. Patent No. 5,807,324.

Andrews discloses the applicant's invention as claimed with the exception of providing a tip that is J-shaped.

Griffin discloses a steerable catheter that does provide a tip that is J-shaped. Therefore it would be obvious to modify Andrews's invention by stating that the tip is J-shaped so that one knows the limitations of the invention.

Claims 8, 9, 10, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. U.S. Patent No. 5,865,721 in view of Valley et al. U.S. Patent No. 5,795,325.

Referring to claim 8, Andrews discloses the applicant's invention as claimed with the exception of providing a fiberoptic sensor fixed at the tip.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a fiberoptic sensor (330) connected at the tip (332). Therefore it would be obvious to modify Andrews's invention by providing a fiberoptic sensor fixed at the tip for better accuracy.

Referring to claim 9, Andrews discloses the applicant's invention as claimed with the exception of providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the balloon membrane.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the balloon membrane. Therefore it would be obvious to modify Andrews's invention by providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the balloon membrane in order to increase the accuracy.

Referring to claim 10, Andrews discloses the applicant's invention as claimed with the exception of providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber

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extending from the sensor through a space defined by the balloon membrane where the fiber is being sandwiched between the stylet and a thin walled tube disposed over the stylet.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the balloon membrane where the fiber is being sandwiched between the stylet and a thin walled tube disposed over the stylet. Therefore it would be obvious to modify Andrews's invention by providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the balloon membrane where the fiber is being sandwiched between the stylet and a thin walled tube disposed over the stylet so that one knows the limitations of the invention.

Referring to claim 11, Andrews discloses the applicant's invention as claimed with the exception of providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the ball membrane wherein the fiber is being embedded in the stylet.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the ball membrane wherein the fiber is being embedded in the stylet. Therefore it would be obvious to modify Andrews's invention by providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the ball membrane wherein the fiber is being embedded in the stylet so that one knows the limitations of the invention.

Referring to claim 12, Andrews discloses the applicant's invention as claimed with the exception of providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the balloon membrane where the fiber passes through the tube.

Valley discloses methods and apparatus for anchoring an occluding member that does provide a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the ball membrane where the fiber passes through the tube. Therefore it would be obvious to modify Andrews's invention by providing a tip that has a fiberoptic sensor fixed to it and a fiberoptic fiber extending from the sensor through a space defined by the ball membrane where the fiber passes through the tube so that one knows the limitations of the invention.

Claims 13, 14, 15, 16, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andrews et al. U.S. Patent No. 5,865,721 in view of Valley et al. U.S. Patent No. 5,795,125 as applied to claims 8 through 10 above, and further in view of Weldon et al. U.S. Patent No. 5,419,765.

Referring to claim 13, Andrew discloses the applicant's as claimed with the exception of providing a tip that comprises a pocket.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that provides a pocket. Therefore it would be obvious to modify Andrews's invention by providing a balloon catheter that comprises a pocket so that one knows the limitations of the invention.

Referring to claim 14, Andrews discloses the applicant's invention as claimed with the exception of providing a pocket that extends from the distal sloping portion to a point between the distal sloping portion and a proximal end of the tip.

Weldon discloses a wound treating device and method for treating wounds that does provide a balloon catheter that provides a pocket that extends from the distal sloping portion to a point between the distal sloping portion and a proximal end of the tip. Therefore it would be obvious to modify Andrews's invention by providing a pocket that extends from the distal sloping portion to a point between the distal sloping portion and a proximal end of the tip in order to deliver the treating agent quickly.

Referring to claim 15, Andrews discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises a pocket that is filled with a protective material.

Weldon discloses a wound treating device and method that does provide a balloon catheter that states that the pocket can be filled with any desired material. Therefore it would be obvious to modify Andrews's invention by providing a balloon catheter that states that the pocket can be filled with protective material or any desired material so that one knows the limitations of the invention.

Referring to claim 16, Andrews discloses the applicant's invention as claimed with the exception of providing a balloon catheter that comprises a pocket that is filled with a gel.

Weldon discloses a wound treating device and method that does provide a balloon catheter that states that the pocket can be filled with any desired material. Therefore it would be obvious to modify Andrews's invention by providing a balloon catheter that states that the

socket can be filled with gel or any desired material so that one knows the limitations of the invention.

Referring to claim 17, Andrews discloses the applicant's invention as claimed with the exception of providing a pocket that is filled with a protective material and wherein the pocket is sealed by a membrane.

Weldon discloses a wound treating device and method that does provide a balloon catheter that states that the pocket can be filled with any desired material such as protective material and is sealed by a membrane. Therefore it would be obvious to modify Andrews's invention by providing a balloon catheter that comprises a pocket that can be filled with any desired material such as protective material and is sealed by a membrane so that one knows the limitations of the invention and that the treating agent can be sealed in a tight environment.

Referring to claim 18, Andrews discloses the applicant's invention as claimed with the exception of providing a pocket that is filled with a protective material and wherein the pocket is sealed by a balloon membrane.

Weldon discloses a wound treating device and method that does provide a balloon catheter that states that the pocket can be filled with any desired material such as protective material and is sealed by a balloon membrane. Therefore it would be obvious to modify Andrew's invention by providing a balloon catheter that states that the pocket can be filled with any desired material such as protective material and is sealed by a balloon membrane so that one knows the limitations of the invention.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP
September 27, 2002

Henry Bennett
Supervisory Patent Examiner
Group 3700

